ATTACHMENT A

US005292331A

United States Patent [19]

Boneau

[11] **Patent Number: 5,292,331**

[45] **Date of Patent: Mar. 8, 1994**

[54] **ENDOVASCULAR SUPPORT DEVICE**

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[73] Assignee: **Applied Vascular Engineering, Inc.**, Santa Rosa, Calif.

[21] Appl. No.: **398,180**

[22] Filed: **Aug. 24, 1989**

[51] **Int. Cl.**[5] **A61M 29/00**

[52] **U.S. Cl.** **606/198**; 623/1

[58] **Field of Search** 606/108, 194, 198, 191; 600/36; 623/1, 11, 12

[56] **References Cited**

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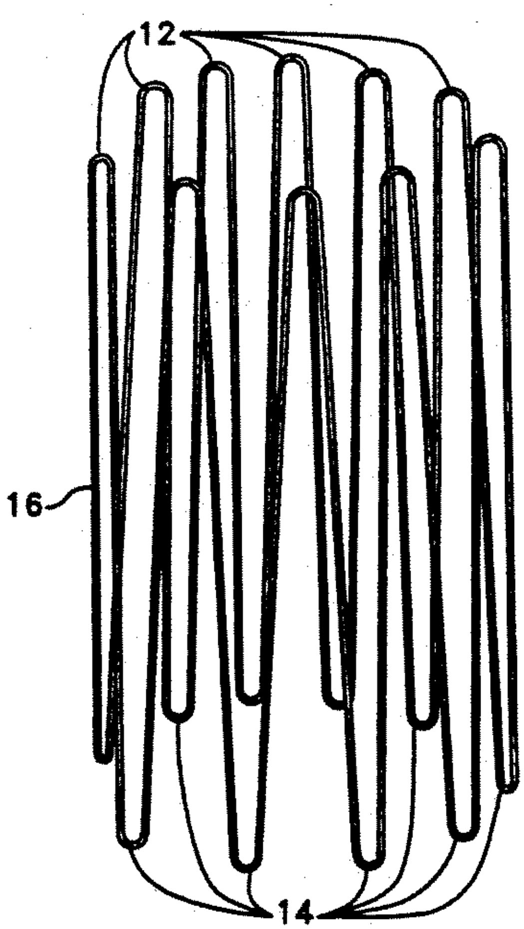
Primary Examiner—Michael H. Thaler
Attorney, Agent, or Firm—James E. Eakin

[57] **ABSTRACT**

An endovascular support device for treatment of chronic restenosis or other vascular narrowing is disclosed together with a method of manufacture and a method for delivering a plurality of such devices to an affected area of a vessel. In a preferred embodiment, the endovascular support device comprises a unitary wire-like structure configured to form a plurality of upper and lower peaks which may be compressed for delivery to an affected area of a coronary or peripheral vessel in a human, and then expanded to maintain a passageway through the vessel.

7 Claims, 3 Drawing Sheets



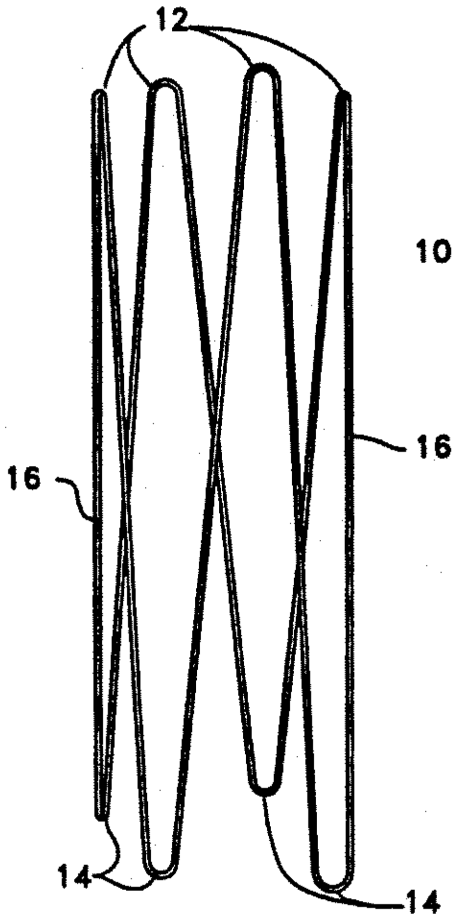


Figure 1

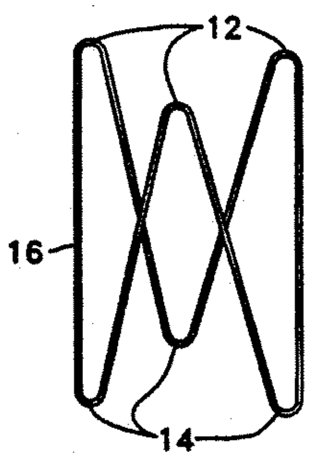


Figure 6a

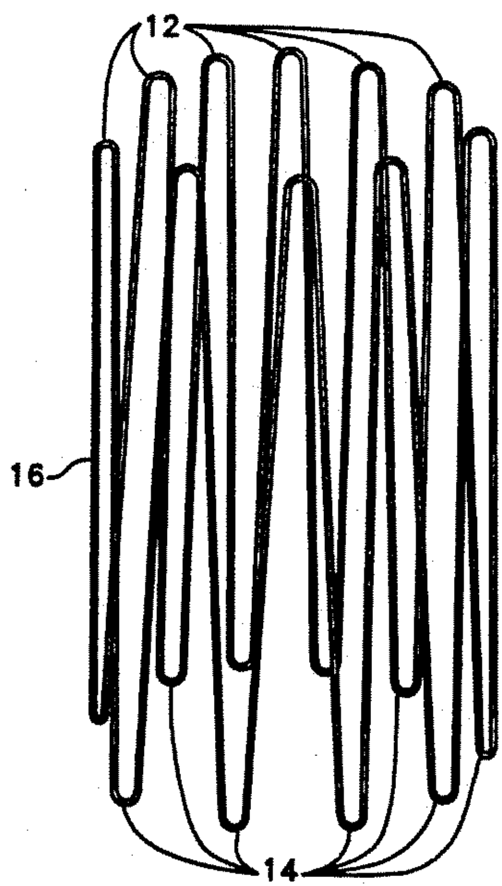


Figure 6b

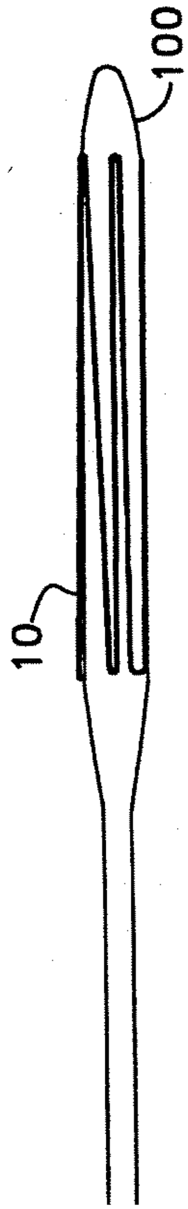


Figure 2

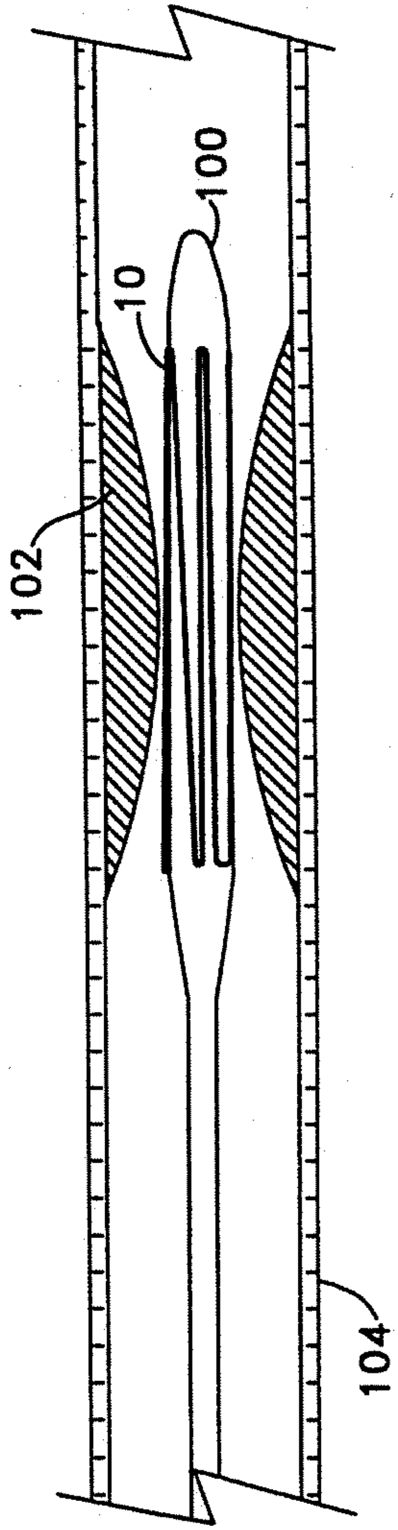


Figure 3

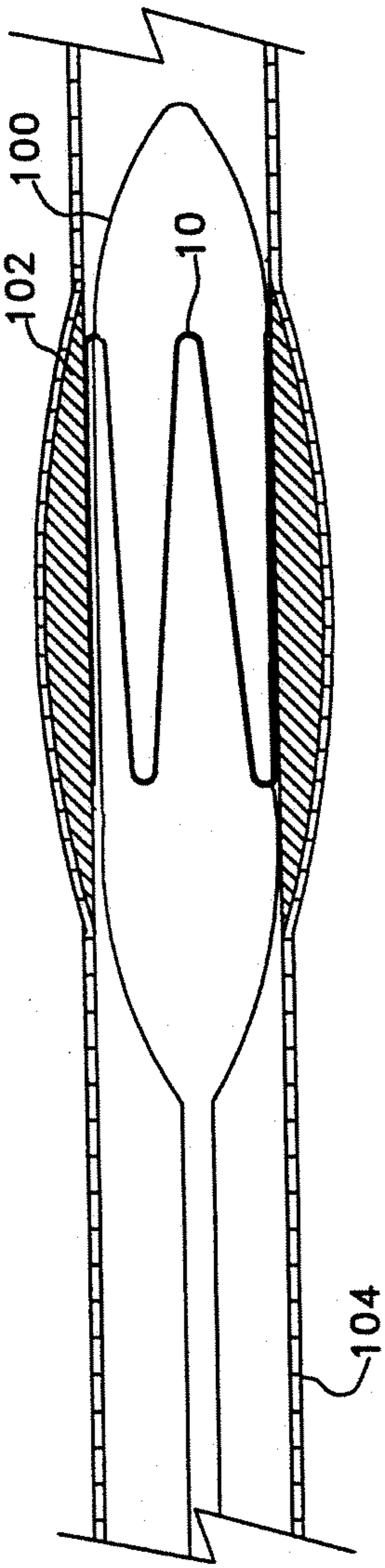


Figure 4

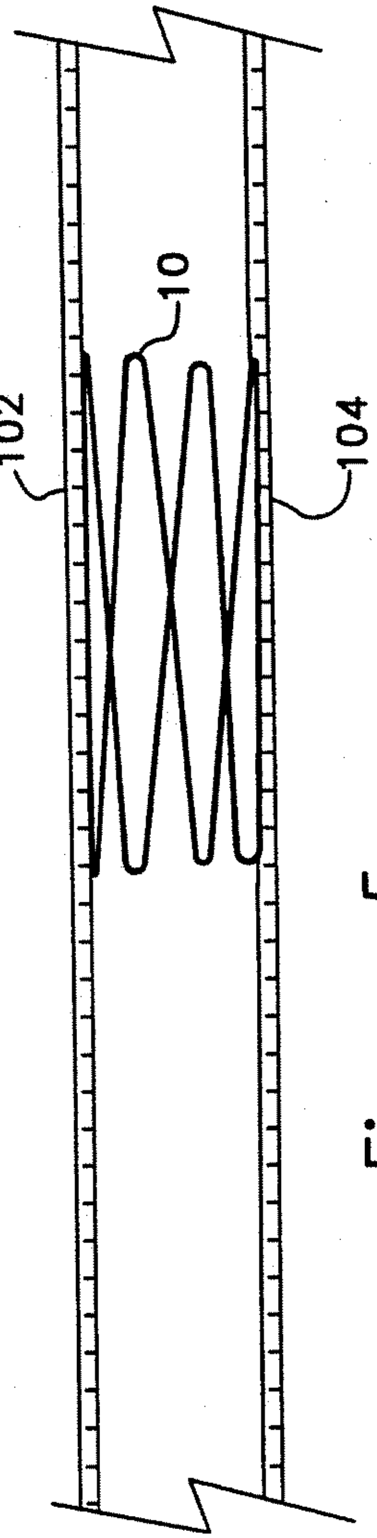


Figure 5

ENDOVASCULAR SUPPORT DEVICE

FIELD OF THE INVENTION

The present invention relates generally to medical devices, and particularly relates to implantable devices for treating narrowing of coronary or peripheral vessels in humans.

BACKGROUND OF THE INVENTION

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

The most impelling development in the past decade for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to simply as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon within the narrowed lumen of the coronary artery. Radial expansion of the coronary artery occurs in several different dimensions and is related to the nature of the plaque. Soft, fatty plaque deposits are flattened by the balloon and hardened deposits are cracked and split to enlarge the lumen. The wall of the artery itself is also stretched when the balloon is inflated.

PTCA is performed as follows: A thin-walled, hollow guiding catheter is typically introduced into the body via a relatively large vessel, such as the femoral artery in the groin area or the brachial artery in the arm. Access to the femoral artery in achieved by introducing a large bore needle directly into the femoral artery, a procedure known as the Seldinger Technique. Once access to the femoral artery is achieved, a short hollow sheath is inserted to maintain a passageway during PTCA. The flexible guiding catheter, which is typically polymer coated, and lined with Teflon, is inserted through the sheath into the femoral artery. The guiding catheter is advanced through the femoral artery into the iliac artery and into the ascending aorta. Further advancement of the flexible catheter involves the negotiation of an approximately 180 degree turn through the aortic arch to allow the guiding catheter to descend into the aortic cusp where entry may be gained to either the left or the right coronary artery, as desired.

After the guiding catheter is advanced to the ostium of the coronary artery to by treated by PTCA, a flexible guidewire is inserted into the guiding catheter through a balloon and advanced to the area to be treated. The guidewire provides the necessary steerability for lesion passage. The guidewire is advanced across the lesion, or "wires" the lesion, in preparation for the advancement of a polyethylene, polyvinyl chloride, polyolefin, or other suitable substance balloon catheter across the guide wire. The balloon, or dilatation, catheter is placed into position by sliding it along the guide wire. The use of the relatively rigid guide wire is necessary to advance the catheter through the narrowed lumen of the artery and to direct the balloon, which is typically quite flexible, across the lesion. Radiopaque markers in the balloon segment of the catheter facilitate positioning across the lesion. The balloon catheter is then inflated

with contrast material to permit fluoroscopic viewing during treatment. The balloon is alternately inflated and deflated until the lumen of the artery is satisfactorily enlarged.

Unfortunately, while the affected artery can be enlarged, in some instances the vessel restenoses chronically, or closes down acutely, negating the positive effect of the angioplasty procedure. In the past, such restenosis has frequently necessitated repeat PTCA or open heart surgery. While such restenosis does not occur in the majority of cases, it occurs frequently enough that such complications comprise a significant percentage of the overall failures of the PTCA procedure, for example, twenty-five to thirty-five percent of such failures.

To lessen the risk of restenosis, various devices have been proposed for mechanically keeping the affected vessel open after completion of the angioplasty procedure. Such mechanical endoprosthetic devices, which are generally referred to as stents, are typically inserted into the vessel, positioned across the lesion, and then expanded to keep the passageway clear. Effectively, the stent overcomes the natural tendency of the vessel walls of some patients to close back down, thereby maintaining a more normal flow of blood through that vessel than would be possible if the stent were not in place.

Various types of stents have been proposed, although to date none has proven satisfactory. One proposed stent involves a tube of stainless wire braid. During insertion, the tube is positioned along a delivery device, such as a catheter, in extended form, making the tube diameter as small as possible. When the stent is positioned across the lesion, it is expanded, causing the length of the tube to contract and the diameter to expand. Depending on the materials used in construction of the stent, the tube maintains the new shape either through mechanical force or otherwise. For example, one such stent is a self-expanding stainless steel wire braid. Other forms of stents include various types tubular metallic cylinders expanded by balloon dilatation. One such device is referred to as the Palmaz stent, discussed further below.

Another form of stent is a heat expandable device. This device, originally designed using NITINOL by Dotter has recently been modified to a new tin-coated, heat expandable coil by Regan. The stent is delivered to the affected area on a catheter capable of receiving heated fluids. Once properly positioned, heated saline is passed through the portion of the catheter on which the stent is located, causing the stent to expand. Numerous difficulties have been encountered with this device, including difficulty in obtaining reliable expansion, and difficulties in maintaining the stent in its expanded state.

Perhaps the most popular stent presently under investigation in the United States is referred to as the Palmaz stent. The Palmaz stent involves what may be thought of as a stainless steel cylinder having a number of slits in its circumference, resulting in a mesh when expanded. The stainless steel cylinder is delivered to the affected area by means of a balloon catheter, and is then expanded to the proper size by inflating the balloon.

Significant difficulties have been encountered with all prior art stents. Eac has its percentage of thrombosis, restenosis and tissue in-growth, as well as varying degrees of difficulty in deployment. Another difficulty with at least some of prior art stents is that they do not readily conform to the vessel shape. In addition, the

relatively long length of such prior art stents has made it difficult to treat curved vessels, and has also effectively prevented successful implantation of multiple such stents. Anticoagulants have historically been required at least for the first three months after placement. These and other complications have resulted in a low level of acceptance for such stents within the medical community, and to date stents have not been accepted as a practical method for treating chronic restenosis.

Thus there has been a long felt need for a stent which is effective to maintain a vessel open, without resulting in significant thrombosis, which may be easily delivered to the affected area, easily expanded to the desired size, easily conformed to the affected vessel, and easily used in multiples to treat curved vessels and varying lengths of lesions.

SUMMARY OF THE INVENTION

The present invention substantially reduces the complications and overcomes the limitations of the prior art devices. The endovascular support device of the present invention comprises a device having very low mass which is capable of being delivered to the affected area by means of a slightly modified conventional balloon catheter similar to that used in a standard balloon angioplasty procedure.

The support device of the present invention may then be expanded by normal expansion of the balloon catheter used to deliver the stent to the affected area, and its size can be adjusted within a relatively broad range in accordance with the diagnosis of the treating physician.

Because of the range of diameters through which the support device of the present invention may be expanded, it may be custom expanded to the specific lesion diameter, and is readily conformable to the vessel shape. In addition, a plurality of support devices of the present invention may be readily implanted in a number commensurate with the length of the lesion under treatment. As a result, curved or "S" shaped vessels may be treated.

The stent, or endovascular support device, of the present invention may preferably be comprised of implantable quality high grade stainless steel, machined specially for intravascular applications. The support device may comprise, in effect, a metal circle or ellipsoid formed to create a plurality of axial bends, thereby permitting compression of the stent onto a delivery catheter, and subsequent expansion once in place at the affected area.

It is one object of the present invention to provide a stent which substantially overcomes the limitations of the prior art.

It is a further object of the present invention to provide a stent capable of being implanted simply and reliably.

Another object of the present invention is to provide a stent which does not result in significant thrombosis at the point of implant.

Yet another object of the present invention is to provide a stent which can be selectively sized in accordance with the anatomic configuration dictated by the lesion itself.

A still further object of the present invention is to provide a method for supplying an endovascular support device which permits a plurality of such devices to be implanted commensurate with the length of the lesion under treatment.

These and other objects of the present invention can be better appreciated from the following detailed description of the invention, taken in conjunction with the attached drawings.

FIGURES

FIG. 1 shows a perspective view of an endovascular support device constructed according to the present invention, in its expanded form.

FIG. 2 shows a support device constructed according to the present invention and compressed onto a balloon catheter.

FIG. 3 shows a support device compressed onto a balloon catheter as shown in FIG. 2, and positioned within a sectioned portion of an affected area of a artery or other vessel.

FIG. 4 shows a support device according to the present invention in its expanded form within a sectioned portion of a vessel including a lesion.

FIG. 5 shows a support device of the present invention in its expanded form within a sectioned portion of a lesion after removal of the balloon catheter.

FIGS. *6a–b* show alternative configurations of a support device according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring first to FIG. 1, an endovascular support device **10**, referred to hereinafter more conveniently as a stent, constructed in accordance with the present invention can be seen in perspective view. The stent **10** of FIG. 1 is shown in its expanded form, prior to compression over a suitable delivery system as discussed in detail hereinafter.

In a preferred embodiment, the stent **10** comprises a single piece of material, bent to form a plurality of upper axial turns **12** and lower axial turns **14**. In the embodiment shown in FIG. 1, four upper turns **12** are connected to the four lower turns **14** by substantially straight segments **16**. The axial turns **12** and **14** can be seen to permit the stent **10** to be compressed or expanded over a wide range while still maintaining significant mechanical force, such as required to prevent a vessel from restenosing. While a preferred embodiment comprises a single piece of material, in some instances a suitably welded wire may be acceptable.

It will be appreciated that the number of turns **12** and **14** can vary over a reasonably wide range, and may in fact vary between two and ten such turns or peaks. However, it is currently believed that the optimum number of turns or peaks will range between three and five for most applications, and particularly for cardiovascular applications.

The stent **10** is preferably constructed of implantable materials having good mechanical strength. An embodiment which has proven successful in preliminary testing is machined from 316LSS implantable quality stainless steel bar stock. The bar stock is machined to form substantially a toroid, which is then acid etched in phosphoric and sulfuric acid at approximately 180° to 185° to break the edges. The etched toroid is then plated with copper to avoid galling and to provide lubricity.

The copper plated toroid is then bent to the shape of the stent **10** shown in FIG. 1, after which the copper plating is stripped from the stent. The stent is then returned to the acid bath to reduce the wire size to the desired diameter, which is in the range of 0.002″ to 0.025″. It is presently believed that the optimum wire

size for the final product is in the range of 0.008" to 0.009". It will be appreciated that the strength of the stent—that is, its ability to prevent restenosis—is inversely proportional to the number of peaks or turns in the stent, so that stents having a greater number of turns will typically be formed of larger wire diameters. Finally, although not required in all cases, the outside of the stent may be selectively plated with platinum to provide improved visibility during fluoroscopy. The cross-sectional shape of the finished stent may be circular, ellipsoidal, rectangular, hexagonal, square, or other polygon, although at present it is believed that circular or ellipsoidal may be preferable.

The minimum length of the stent, or the distance between the upper turns **12** and lower turns **14**, is determined in large measure by the size of the vessel into which the stent will be implanted. The stent **10** will preferably be of sufficient length as to maintain its axial orientation within the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis. Typical cardiovascular vessels into which the stent **10** might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding stents may range from one millimeter to two centimeters in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters has been performed with good success outside the United States, and testing on animals is also ongoing.

Once the wire size of the stent **10** has been reduced to the desired size, the stent **10** may be crimped onto a balloon **100**, as shown in FIG. **2**, for delivery to the affected region **102** of a vessel **104** such as a coronary artery. For the sake of simplicity, the multiple layers of the vessel wall **104** are shown as a single layer, although it will be understood by those skilled in the art that the lesion typically is a plaque deposit within the intima of the vessel **104**.

One suitable balloon for delivery of the stent **10** is manufactured by Advanced Cardiovascular Systems, Inc., of Santa Clara, Calif. ("ACS"), and is eight millimeters in length with Microglide ® on the shaft only. The stent-carrying balloon **100** is then advanced to the affected area and across the lesion **102** in a conventional manner, such as by use of a guide wire and a guide catheter (not shown). A suitable guide wire is the 0.014" Hi Torque Floppy manufactured by ACS, and a suitable guiding catheter is the ET.076 lumen guide catheter, also manufactured by ACS.

Once the balloon **100** is in place across the lesion **102**, as shown in FIG. **3**, the balloon **100** may be inflated, again substantially in a conventional manner. In selecting a balloon, it is helpful to ensure that the balloon will provide radially uniform inflation so that the stent **10** will expand equally along each of the peaks. The inflation of the balloon **100**, shown in FIG. **4**, causes the expansion of the stent **10**, from its crimped configuration back to a shape substantially like that shown in FIG. **1**. The amount of inflation, and commensurate amount of expansion of the stent **10**, may be varied as dictated by the lesion itself, making the stent of the

present invention particularly flexible in the treatment of chronic restenosis.

Because of the inflation of the balloon, the lesion **102** in the vessel **104** is expanded, and causes the arterial wall of the vessel **104** to bulge radially, as simplistically depicted in FIG. **4**. At the same time, the plaque deposited within the intima of the vessel is displaced and thinned, and the stent **10** is embedded in the plaque or other fibrotic material adhering to the intima of the vessel **104**.

Following inflation of the balloon **100** and expansion of the stent **10** within the vessel **104**, the balloon is deflated and removed. The exterior wall of the vessel **104** returns to its original shape through elastic recoil. The stent **10**, however, remains in its expanded form within the vessel, and prevents further restenosis of the vessel. The stent maintains an open passageway through the vessel, as shown in FIG. **4**, so long as the tendency toward restenosis is not greater than the mechanical strength of the stent **10**. Because of the low mass of the support device **10** of the present invention, thrombosis is less likely to occur. Ideally, the displacement of the plaque deposits and the implantation of the stent **10** will result in a smooth inside diameter of the vessel **104**, although this ideal cannot be achieved in all cases.

One of the advantages of the stent **10** is that multiple stents may be used in the treatment of a single lesion. Thus, for example, in the event the affected area shown in FIGS. **3** and **4** was longer than the stent **10**, additional stents **10** could be positioned elsewhere along the lesion to prevent restenosis. In preliminary testing, up to four stents have been used successfully along a single lesion. Due to the conformability of the stent **10**, not only can varying lesion lengths be treated, but curved vessels and "S" shaped vessels may also be treated by the present invention. In instances where it is known in advance that multiple stents will be the preferred method of treatment, a plurality of such stents may be positioned along a single balloon catheter for simultaneous delivery to the affected area.

As discussed above, the number of peaks or turns **12** and **14** in the stent **10** may vary between two and ten. To this end, shown in FIGS. **6a** and **6b** are two alternative configurations of the stent **10**. The alternative embodiment shown in **6a** can be seen to have three upper and three lower peaks or turns, while the embodiment shown in FIG. **6b** can be seen to have ten upper and ten lower peaks.

While the primary application for the stent **10** is presently believed to be treatment of cardiovascular disease such as atherosclerosis or other forms of coronary narrowing, the stent **10** of the present invention may also be used for treatment of narrowed vessels in the kidney, leg, carotid, or elsewhere in the body. In such other vessels, the size of the stent may need to be adjusted to compensate for the differing sizes of the vessel to be treated, bearing in mind the sizing guidelines provided above.

Having fully described a preferred embodiment of the invention, those skilled in the art will immediately appreciate, given the teachings herein, that numerous alternatives and equivalents exist which do not depart from the present invention. It is therefore to be understood that the present invention is not to be limited by the foregoing description, but only by the appended claims.

I claim:

1. A stent for implantation within a vessel within the human body comprising a plurality of N substantially straight segments of wire-like material, each segment having a first and second ends wherein the first end of a first segment is connected to the first end of a second segment, the second end of the second segment is connected to the second end of the third segment, the first end of the third segment is connected to the first end of the fourth segment, and so on until the second end of the Nth segment is connected to the second end of the first segment, with no segment overlapping any other segment and the plurality of segments being capable of being compressed onto a catheter for delivery to an affected area of a vessel and then forcibly expanded to maintain the affected area of a vessel at a diameter larger than if the support device were not implanted.

2. The stent of claim 1 wherein the value of N is between six and twenty.

3. The stent of claim 2 wherein the plurality of segments of wire-like material are formed as a single unit and then bent to form the plurality of segments.

4. The stent of claim 3 wherein the plurality of segments are formed of surgical stainless steel.

5. The stent of claim 4 wherein the plurality of segments are plated with platinum.

6. A stent for implantation in a vessel within the human body comprising a unitary wire-like circular member bent to form a plurality of N substantially straight, non-overlapping segments wherein each segment has a first end and a second end, and the first end of the first segment is connected to the first end of the second segment, the second end of the second segment is connected to the second end of the third segment, the first end of the third segment is connect to the first end of the fourth segment, and so on until the second end of the Nth segment is connected to the second end of the first segment, the stent being compressed onto a catheter for delivery to an affected area of a vessel and then forcibly expanded to maintain the affected area of a vessel at a diameter larger than if the support device were not implanted, the value of N being between six and twenty.

7. The stent of claim 6 wherein the stent is formed of surgical stainless steel and plated with platinum.

* * * * *

ATTACHMENT B

US005800509A

United States Patent [19]

Boneau

[11] Patent Number: 5,800,509

[45] Date of Patent: Sep. 1, 1998

[54] **METHOD OF MAKING ENDOVASCULAR SUPPORT DEVICE**

[75] Inventor: **Michael D. Boneau**, Campbell, Calif.

[73] Assignee: **Arterial Vascular Engineering, Inc.**, Santa Rosa, Calif.

[21] Appl. No.: **465,842**

[22] Filed: **Jun. 6, 1995**

Related U.S. Application Data

[62] Division of Ser. No. 172,420, Dec. 22, 1993, abandoned, which is a division of Ser. No. 398,180, Aug. 24, 1989, Pat. No. 5,292,331.

[51] **Int. Cl.**[6] **A61F 2/06**; A61F 2/04

[52] **U.S. Cl.** **623/1**; 600/36

[58] **Field of Search** 623/1, 11, 12; 606/194, 195, 198; 600/36

[56] **References Cited**

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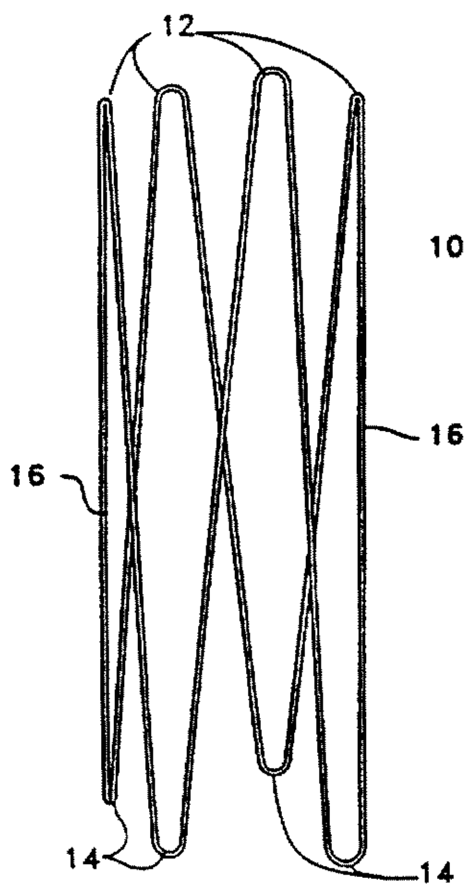
Primary Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Richard L. Klein

[57] **ABSTRACT**

An endovascular support device for treatment of chronic restenosis or other vascular narrowing is disclosed together with a method of manufacture and a method for delivering a plurality of such devices to an affected area of a vessel. In a preferred embodiment, the endovascular support device comprises a unitary wire-like structure configured to form a plurality of upper and lower peaks which may be compressed for delivery to an affected area of a coronary or peripheral vessel in a human, and then expanded to maintain a passageway through the vessel.

13 Claims, 3 Drawing Sheets



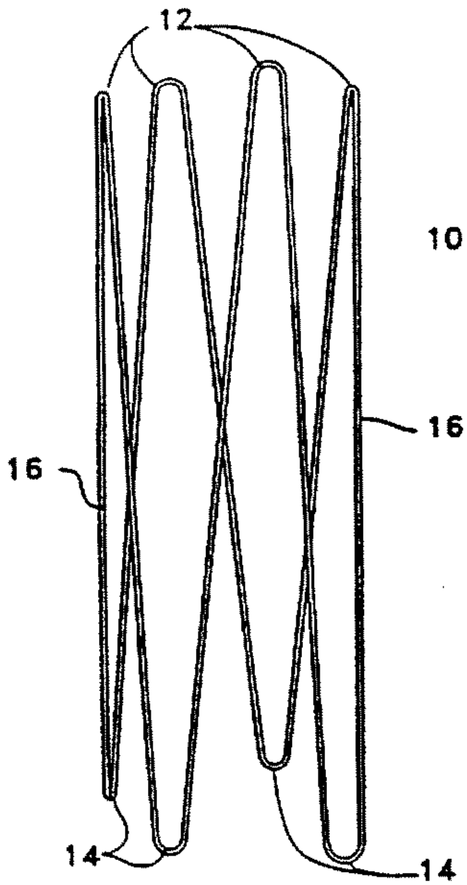


Figure 1

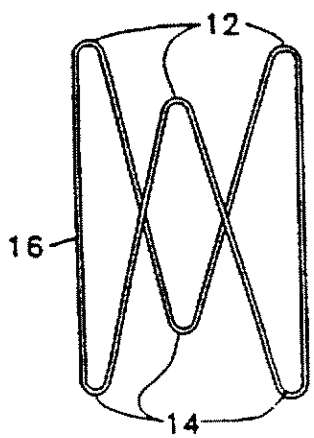


Figure 6a

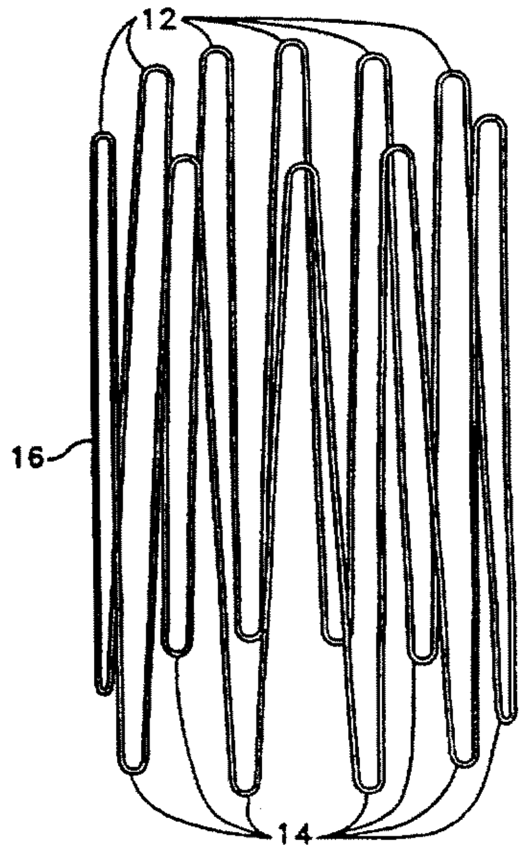


Figure 6b

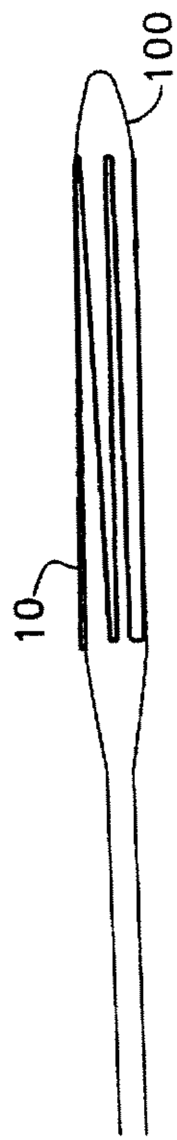


Figure 2

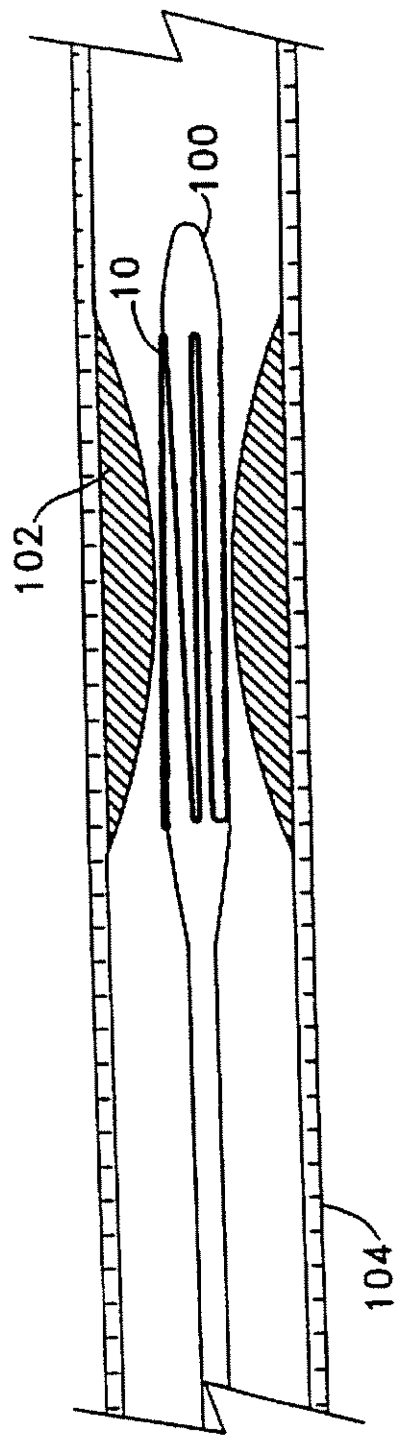


Figure 3

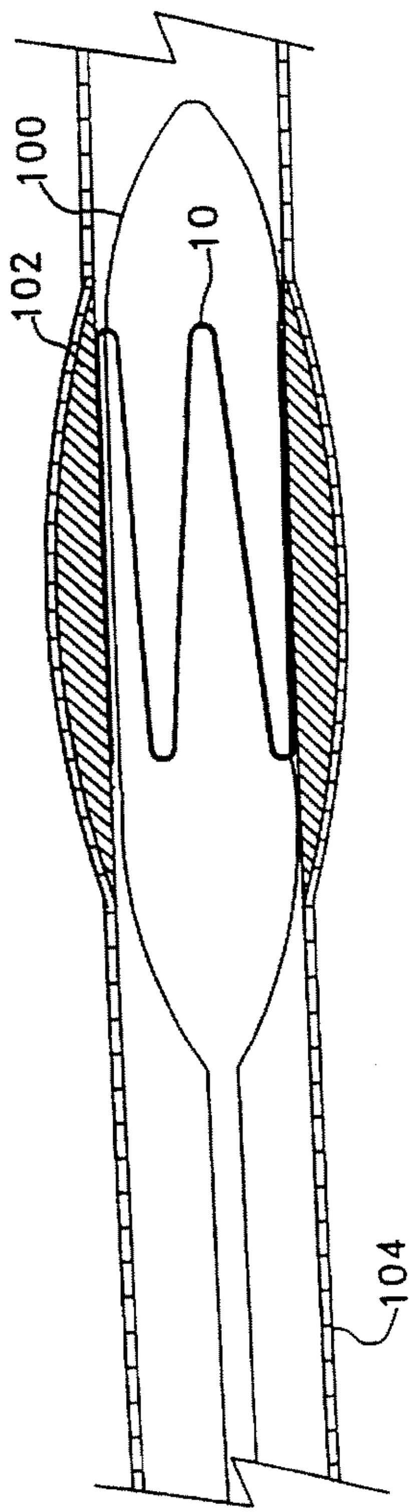


Figure 4

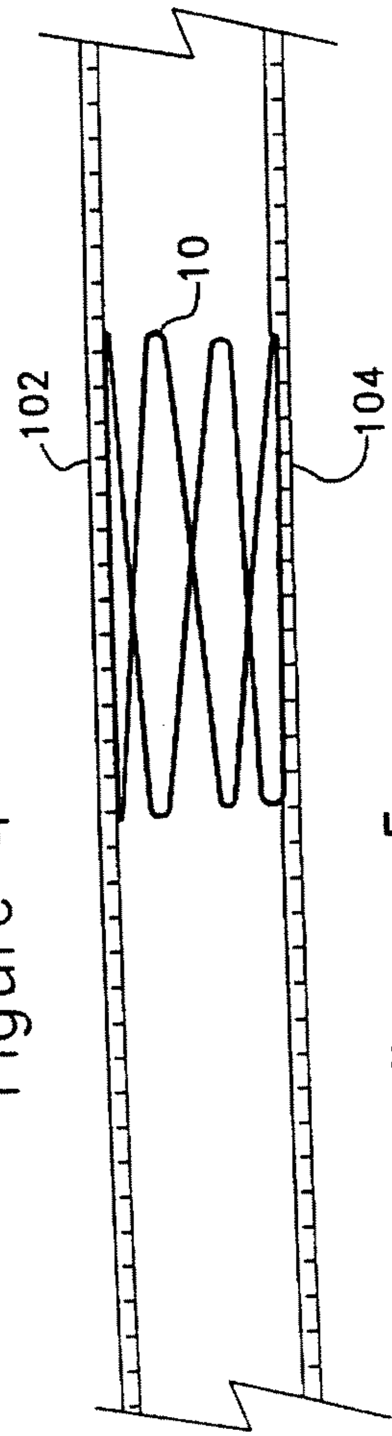


Figure 5

METHOD OF MAKING ENDOVASCULAR SUPPORT DEVICE

This application is a division of application Ser. No. 08/172,420, filed Dec. 22, 1993, now abandoned, which is a division of application Ser. No. 07/398,180, filed Aug. 24, 1989, now U.S. Pat. No. 5,292,331.

SPECIFICATION

1. Field of the Invention

The present invention relates generally to medical devices, and particularly relates to implantable devices for treating narrowing of coronary or peripheral vessels in humans.

2. Background of the Invention

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

The most impelling development in the past decade for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to simply as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon within the narrowed lumen of the coronary artery. Radial expansion of the coronary artery occurs in several different dimensions and is related to the nature of the plaque. Soft, fatty plaque deposits are flattened by the balloon and hardened deposits are cracked and split to enlarge the lumen. The wall of the artery itself is also stretched when the balloon is inflated.

PTCA is performed as follows: A thin-walled, hollow guiding catheter is typically introduced into the body via a relatively large vessel, such as the femoral artery in the groin area or the brachial artery in the arm. Access to the femoral artery is achieved by introducing a large bore needle directly into the femoral artery, a procedure known as the Seldinger Technique. Once access to the femoral artery is achieved, a short hollow sheath is inserted to maintain a passageway during PTCA. The flexible guiding catheter, which is typically polymer coated, and lined with Teflon, is inserted through the sheath into the femoral artery. The guiding catheter is advanced through the femoral artery into the iliac artery and into the ascending aorta. Further advancement of the flexible catheter involves the negotiation of an approximately 180 degree turn through the aortic arch to allow the guiding catheter to descend into the aortic cusp where entry may be gained to either the left or the right coronary artery, as desired.

After the guiding catheter is advanced to the ostium of the coronary artery to be treated by PTCA, a flexible guidewire is inserted into the guiding catheter through a balloon and advanced to the area to be treated. The guidewire provides the necessary steerability for lesion passage. The guidewire is advanced across the lesion, or "wires" the lesion, in preparation for the advancement of a polyethylene, polyvinyl chloride, polyolefin, or other suitable substance balloon catheter across the guide wire. The balloon, or dilatation, catheter is placed into position by sliding it along the guide wire. The use of the relatively rigid guide wire is necessary to advance the catheter through the narrowed lumen of the artery and to direct the balloon, which is typically quite flexible, across the lesion. Radiopaque markers in the balloon segment of the catheter facilitate positioning across the lesion. The balloon catheter is then inflated with contrast material to permit fluoroscopic viewing during treatment. The balloon is alternately inflated and deflated until the lumen of the artery is satisfactorily enlarged.

Unfortunately, while the affected artery can be enlarged, in some instances the vessel restenoses chronically, or closes down acutely, negating the positive effect of the angioplasty procedure. In the past, such restenosis has frequently necessitated repeat PTCA or open heart surgery. While such restenosis does not occur in the majority of cases, it occurs frequently enough that such complications comprise a significant percentage of the overall failures of the PTCA procedure, for example, twenty-five to thirty-five percent of such failures.

To lessen the risk of restenosis, various devices have been proposed for mechanically keeping the affected vessel open after completion of the angioplasty procedure. Such mechanical endoprosthetic devices, which are generally referred to as stents, are typically inserted into the vessel, positioned across the lesion, and then expanded to keep the passageway clear. Effectively, the stent overcomes the natural tendency of the vessel walls of some patients to close back down, thereby maintaining a more normal flow of blood through that vessel than would be possible if the stent were not in place.

Various types of stents have been proposed, although to date none has proven satisfactory. One proposed stent involves a tube of stainless wire braid. During insertion, the tube is positioned along a delivery device, such as a catheter, in extended form, making the tube diameter as small as possible. When the stent is positioned across the lesion, it is expanded, causing the length of the tube to contract and the diameter to expand. Depending on the materials used in construction of the stent, the tube maintains the new shape either through mechanical force or otherwise. For example, one such stent is a self-expanding stainless steel wire braid. Other forms of stents include various types tubular metallic cylinders expanded by balloon dilatation. One such device is referred to as the Palmaz stent, discussed further below.

Another form of stent is a heat expandable device. This device, originally designed using NITINOL by Dotter has recently been modified to a new tin-coated, heat expandable coil by Regan. The stent is delivered to the affected area on a catheter capable of receiving heated fluids. Once properly positioned, heated saline is passed through the portion of the catheter on which the stent is located, causing the stent to expand. Numerous difficulties have been encountered with this device, including difficulty in obtaining reliable expansion, and difficulties in maintaining the stent in its expanded state.

Perhaps the most popular stent presently under investigation in the United States is referred to as the Palmaz stent. The Palmaz stent involves what may be thought of as a stainless steel cylinder having a number of slits in its circumference, resulting in a mesh when expanded. The stainless steel cylinder is delivered to the affected area by means of a balloon catheter, and is then expanded to the proper size by inflating the balloon.

Significant difficulties have been encountered with all prior art stents. Each has its percentage of thrombosis, restenosis and tissue in-growth, as well as varying degrees of difficulty in deployment. Another difficulty with at least some of prior art stents is that they do not readily conform to the vessel shape. In addition, the relatively long length of such prior art stents has made it difficult to treat curved

vessels, and has also effectively prevented successful implantation of multiple such stents. Anticoagulants have historically been required at least for the first three months after placement. These and other complications have resulted in a low level of acceptance for such stents within the medical community, and to date stents have not been accepted as a practical method for treating chronic restenosis.

Thus there has been a long felt need for a stent which is effective to maintain a vessel open, without resulting in significant thrombosis, which may be easily delivered to the affected area, easily expanded to the desired size, easily conformed to the affected vessel, and easily used in multiples to treat curved vessels and varying lengths of lesions.

SUMMARY OF THE INVENTION

The present invention substantially reduces the complications and overcomes the limitations of the prior art devices. The endovascular support device of the present invention comprises a device having very low mass which is capable of being delivered to the affected area by means of a slightly modified conventional balloon catheter similar to that used in a standard balloon angioplasty procedure.

The support device of the present invention may then be expanded by normal expansion of the balloon catheter used to deliver the stent to the affected area, and its size can be adjusted within a relatively broad range in accordance with the diagnosis of the treating physician.

Because of the range of diameters through which the support device of the present invention may be expanded, it may be custom expanded to the specific lesion diameter, and is readily conformable to the vessel shape. In addition, a plurality of support devices of the present invention may be readily implanted in a number commensurate with the length of the lesion under treatment. As a result, curved or "S" shaped vessels may be treated.

The stent, or endovascular support device, of the present invention may preferably be comprised of implantable quality high grade stainless steel, machined specially for intravascular applications. The support device may comprise, in effect, a metal circle or ellipsoid formed to create a plurality of axial bends, thereby permitting compression of the stent onto a delivery catheter, and subsequent expansion once in place at the affected area.

It is one object of the present invention to provide a stent which substantially overcomes the limitations of the prior art.

It is a further object of the present invention to provide a stent capable of being implanted simply and reliably.

Another object of the present invention is to provide a stent which does not result in significant thrombosis at the point of implant.

Yet another object of the present invention is to provide a stent which can be selectively sized in accordance with the anatomic configuration dictated by the lesion itself.

A still further object of the present invention is to provide a method for supplying an endovascular support device which permits a plurality of such devices to be implanted commensurate with the length of the lesion under treatment.

These and other objects of the present invention can be better appreciated from the following detailed description of the invention, taken in conjunction with the attached drawings.

FIGURES

FIG. 1 shows a perspective view of an endovascular support device constructed according to the present invention, in its expanded form.

FIG. 2 shows a support device constructed according to the present invention and compressed onto a balloon catheter.

FIG. 3 shows a support device compressed onto a balloon catheter as shown in FIG. 2, and positioned within a sectioned portion of an affected area of a artery or other vessel.

FIG. 4 shows a support device according to the present invention in its expanded form within a sectioned portion of a vessel including a lesion.

FIG. 5 shows a support device of the present invention in its expanded form within a sectioned portion of a lesion after removal of the balloon catheter.

FIGS. 6*a–b* show alternative configurations of a support device according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring first to FIG. 1, an endovascular support device **10**, referred to hereinafter more conveniently as a stent, constructed in accordance with the present invention can be seen in perspective view. The stent **10** of FIG. 1 is shown in its expanded form, prior to compression over a suitable delivery system as discussed in detail hereinafter.

In a preferred embodiment, the stent **10** comprises a single piece of material, bent to form a plurality of upper axial turns **12** and lower axial turns **14**. In the embodiment shown in FIG. 1, four upper turns **12** are connected to the four lower turns **14** by substantially straight segments **16**. The axial turns **12** and **14** can be seen to permit the stent **10** to be compressed or expanded over a wide range while still maintaining significant mechanical force, such as required to prevent a vessel from restenosing. While a preferred embodiment comprises a single piece of material, in some instances a suitably welded wire may be acceptable.

It will be appreciated that the number of turns **12** and **14** can vary over a reasonably wide range, defined in "N" number of turns, and may in fact vary between two and ten such turns or peaks. However, it is currently believed that the optimum number of turns or peaks will range between three and five for most applications, and particularly for cardiovascular applications.

The stent **10** is preferably constructed of implantable materials having good mechanical strength. An embodiment which has proven successful in preliminary testing is machined from 316LSS implantable quality stainless steel bar stock. The bar stock is machined to form substantially a toroid, which is then acid etched in phosphoric and sulfuric acid at approximately 180. to 185. to break the edges. The etched toroid is then plated with copper to avoid galling and to provide lubricity.

The copper plated toroid is then bent to the shape of the stent **10** shown in FIG. 1, after which the copper plating is stripped from the stent. The stent is then returned to the acid bath to reduce the wire size to the desired diameter, which is in the range of 0.002" to 0.025". It is presently believed that the optimum wire size for the final product is in the range of 0.008" to 0.009". It will be appreciated that the strength of the stent—that is, its ability to prevent restenosis—is inversely proportional to the number of peaks or turns in the stent, so that stents having a greater number of turns will typically be formed of larger wire diameters. Finally, although not required in all cases, the outside of the stent may be selectively plated with platinum to provide improved visibility during fluoroscopy. The cross-sectional shape of the finished stent may be circular, ellipsoidal,

rectangular, hexagonal, square, or other polygon, although at present it is believed that circular or ellipsoidal may be preferable.

The minimum length of the stent, or the distance between the upper turns 12 and lower turns 14, is determined in large measure by the size of the vessel into which the stent will be implanted. The stent 10 will preferably be of sufficient length as to maintain its axial orientation within the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis. Typical cardiovascular vessels into which the stent 10 might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding stents may range from one millimeter to two centimeters in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters has been performed with good success outside the United States, and testing on animals is also ongoing.

Once the wire size of the stent 10 has been reduced to the desired size, the stent 10 may be crimped onto a balloon 100, as shown in FIG. 2, for delivery to the affected region 102 of a vessel 104 such as a coronary artery. For the sake of simplicity, the multiple layers of the vessel wall 104 are shown as a single layer, although it will be understood by those skilled in the art that the lesion typically is a plaque deposit within the intima of the vessel 104.

One suitable balloon for delivery of the stent 10 is manufactured by Advanced Cardiovascular Systems, Inc., of Santa Clara, Calif. ("ACS"), and is eight millimeters in length with Microglide® on the shaft only. The stent-carrying balloon 100 is then advanced to the affected area and across the lesion 102 in a conventional manner, such as by use of a guide wire and a guide catheter (not shown). A suitable guide wire is the 0.014" Hi Torque Floppy manufactured by ACS, and a suitable guiding catheter is the ET.076 lumen guide catheter, also manufactured by ACS.

Once the balloon 100 is in place across the lesion 102, as shown in FIG. 3, the balloon 100 may be inflated, again substantially in a conventional manner. In selecting a balloon, it is helpful to ensure that the balloon will provide radially uniform inflation so that the stent 10 will expand equally along each of the peaks. The inflation of the balloon 100, shown in FIG. 4, causes the expansion of the stent 10 from its crimped configuration back to a shape substantially like that shown in FIG. 1. The amount of inflation, and commensurate amount of expansion of the stent 10, may be varied as dictated by the lesion itself, making the stent of the present invention particularly flexible in the treatment of chronic restenosis.

Because of the inflation of the balloon, the lesion 102 in the vessel 104 is expanded, and causes the arterial wall of the vessel 104 to bulge radially, as simplistically depicted in FIG. 4. At the same time, the plaque deposited within the intima of the vessel is displaced and thinned, and the stent 10 is embedded in the plaque or other fibrotic material adhering to the intima of the vessel 104.

Following inflation of the balloon 100 and expansion of the stent 10 within the vessel 104, the balloon is deflated and removed. The exterior wall of the vessel 104 returns to its original shape through elastic recoil. The stent 10, however, remains in its expanded form within the vessel, and prevents

further restenosis of the vessel. The stent maintains an open passageway through the vessel, as shown in FIG. 4, so long as the tendency toward restenosis is not greater than the mechanical strength of the stent 10. Because of the low mass of the support device 10 of the present invention, thrombosis is less likely to occur. Ideally, the displacement of the plaque deposits and the implantation of the stent 10 will result in a smooth inside diameter of the vessel 104, although this ideal cannot be achieved in all cases.

One of the advantages of the stent 10 is that multiple stents, "M", may be used in the treatment of a single lesion. Thus, for example, in the event the affected area shown in FIGS. 3 and 4 was longer than the stent 10, additional stents 10 could be positioned elsewhere along the lesion to prevent restenosis. In preliminary testing, up to four stents have been used successfully along a single lesion. Due to the conformability of the stent 10, not only can varying lesion lengths be treated, but curved vessels and "S" shaped vessels may also be treated by the present invention. In instances where it is known in advance that multiple stents will be the preferred method of treatment, a plurality of such stents, "M" may be positioned along a single balloon catheter for simultaneous delivery to the affected area.

As discussed above, the number of peaks or turns 12 and 14 in the stent 10, "N" number of turns, may vary between two and ten. To this end, shown in FIGS. *6a* and *6b* are two alternative configurations of the stent 10. The alternative embodiment shown in *6a* can be seen to have three upper and three lower peaks or turns, while the embodiment shown in FIG. *6b* can be seen to have ten upper and ten lower peaks.

While the primary application for the stent 10 is presently believed to be treatment of cardiovascular disease such as atherosclerosis or other forms of coronary narrowing, the stent 10 of the present invention may also be used for treatment of narrowed vessels in the kidney, leg, carotid, or elsewhere in the body. In such other vessels, the size of the stent may need to be adjusted to compensate for the differing sizes of the vessel to be treated, bearing in mind the sizing guidelines provided above.

Having fully described a preferred embodiment of the invention, those skilled in the art will immediately appreciate, given the teachings herein, that numerous alternatives and equivalents exist which do not depart from the present invention. It is therefore to be understood that the present invention is not to be limited by the foregoing description, but only by the appended claims.

I claim:

1. A method of manufacturing an endovascular support device comprising

forming a toroid from a first material,

plating the toroid with a second material having higher lubricity than the first material,

bending the toroid to form a plurality of upper and lower peaks,

stripping off the second material from the toroid, and

reducing the diameter of the bent toroid to a desired size.

2. A method of manufacturing an endovascular support device comprising:

forming a toroid; and

bending the toroid to form a plurality of upper and lower peaks.

3. The method of claim 2 further comprising the step of reducing the diameter of the bent toroid to a desired size.

4. The method of claim 3 wherein the step of reducing the diameter of the toroid is performed by etching.

5. The method of claim 2 further comprising the steps of:

forming a plurality of toroids; and

bending the plurality of toroids to form a plurality of bent toroids having a selectable number of upper and lower peaks.

6. The method of claim 5 including the additional steps of arranging the plurality of bent toroids to form the endovascular support device and reducing the diameter of the plurality of bent toroids to a desired size.

7. The method of claim 6 wherein the plurality of bent toroids forming the endovascular support device are not connected to one another.

8. A method of manufacturing an endovascular support device comprising the steps of:

forming a member having a plurality of upper and lower axial turns connected by substantially straight segments, wherein no straight segment overlaps any other straight segment; and

reducing the cross-section of the member to a desired size.

9. The method of claim 8 wherein at least one of the steps is performed by etching.

10. The method of claim 8 wherein both of the steps are performed by etching.

11. The method of claim 8 further comprising the step of:

forming a plurality of members each having a plurality of upper and lower axial turns connected by substantially straight segments wherein no straight segment overlaps any other straight segment.

12. The method of claim 11 further comprising the step of:

reducing the cross-section of each of the plurality of members to a desired size.

13. The method of claim 11 wherein the plurality of members forming the endovascular support device are not connected to one another.

* * * * *

ATTACHMENT C

US005817152A

United States Patent [19]

Birdsall et al.

[11] Patent Number: 5,817,152

[45] Date of Patent: Oct. 6, 1998

[54] **CONNECTED STENT APPARATUS**

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[21] Appl. No.: **451,270**

[22] Filed: **May 30, 1995**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 326,024, Oct. 19, 1994, abandoned.

[51] **Int. Cl.**[6] **A61F 2/06**

[52] **U.S. Cl.** **623/1**; 623/12; 606/195

[58] **Field of Search** 623/1, 11, 12; 606/191–200

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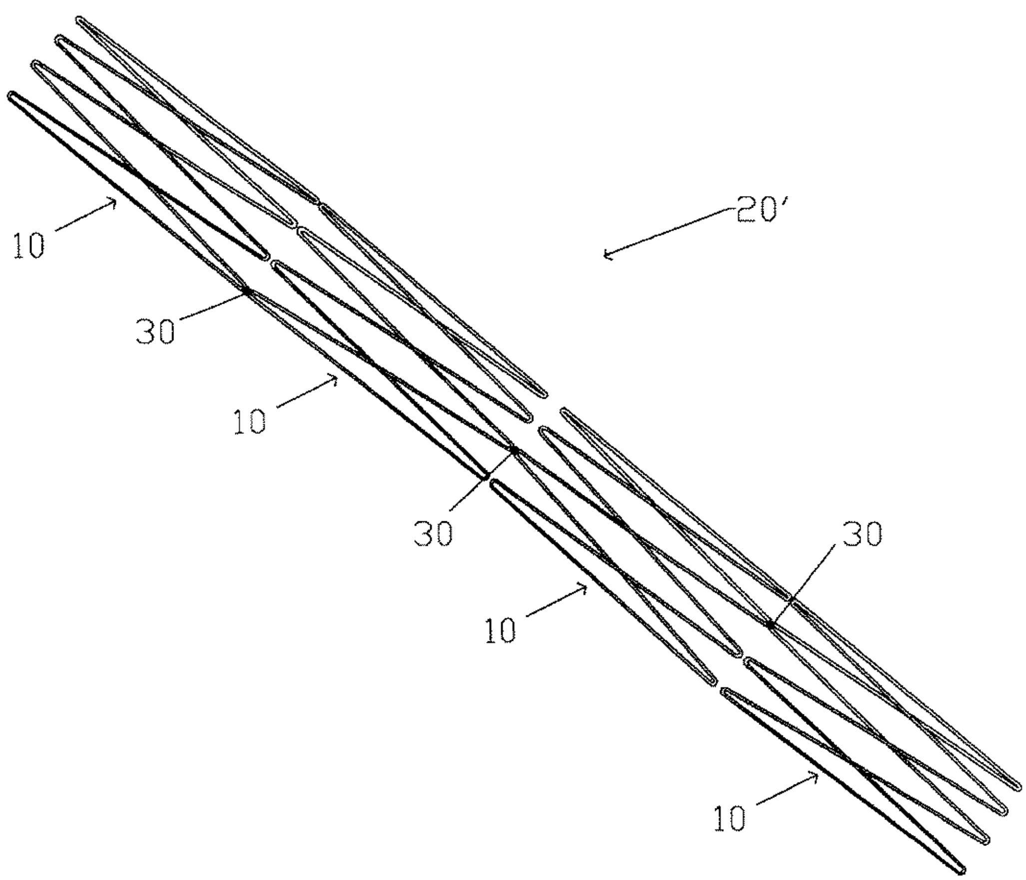
Primary Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Richard L. Klein

[57] **ABSTRACT**

An endoprosthetic device comprises at least two short stent segments welded together to form a connected stent. Each stent segment defines a single wire having straight sections integrally formed between axial turns. The welds are placed between stent segments at one or more aligned adjacent axial turns. The welded connected stent is flexible enough to allow it to pass through sharp turns and to be implanted to conform to the contour of the lesion to be treated. In one aspect of the invention all adjacent axial turns are welded together. In another aspect of the invention, selected adjacent axial turns are welded together to create a generally balanced spiral pattern of welds surrounding the cylindrical connected stent.

14 Claims, 4 Drawing Sheets



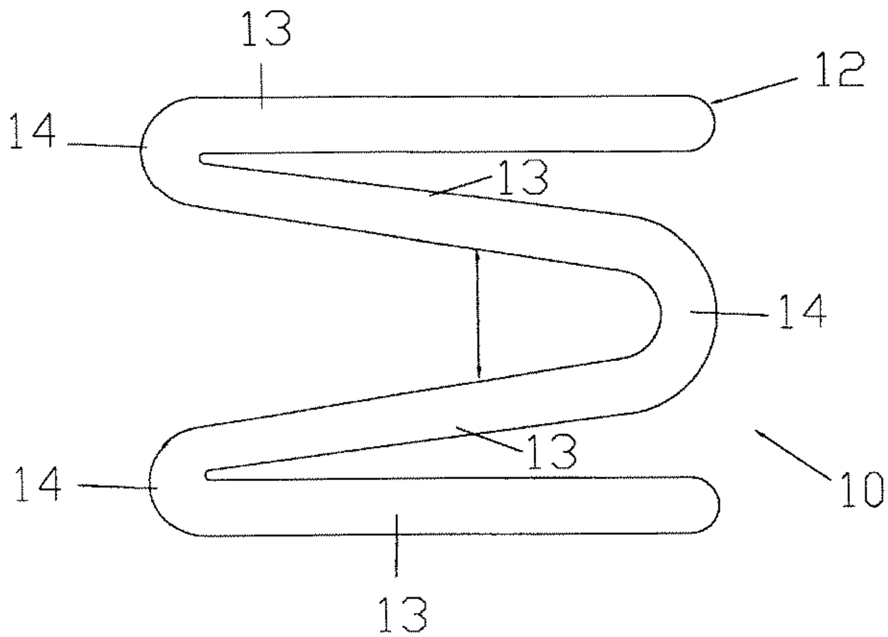


FIG. 1

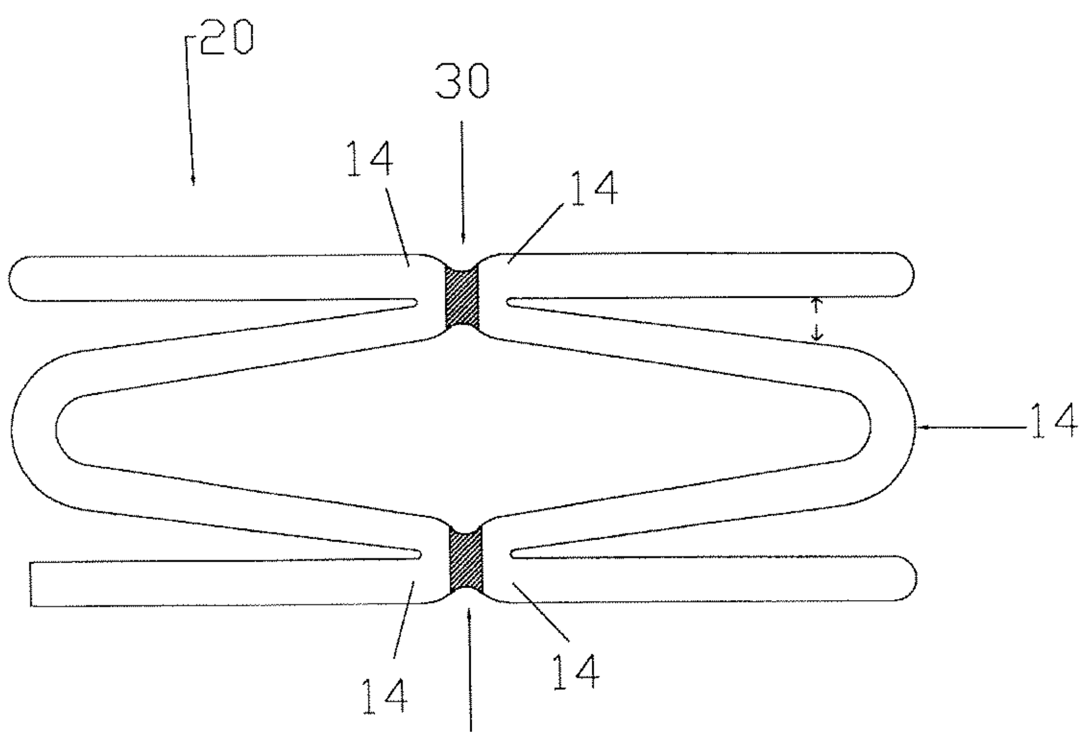


FIG. 3A

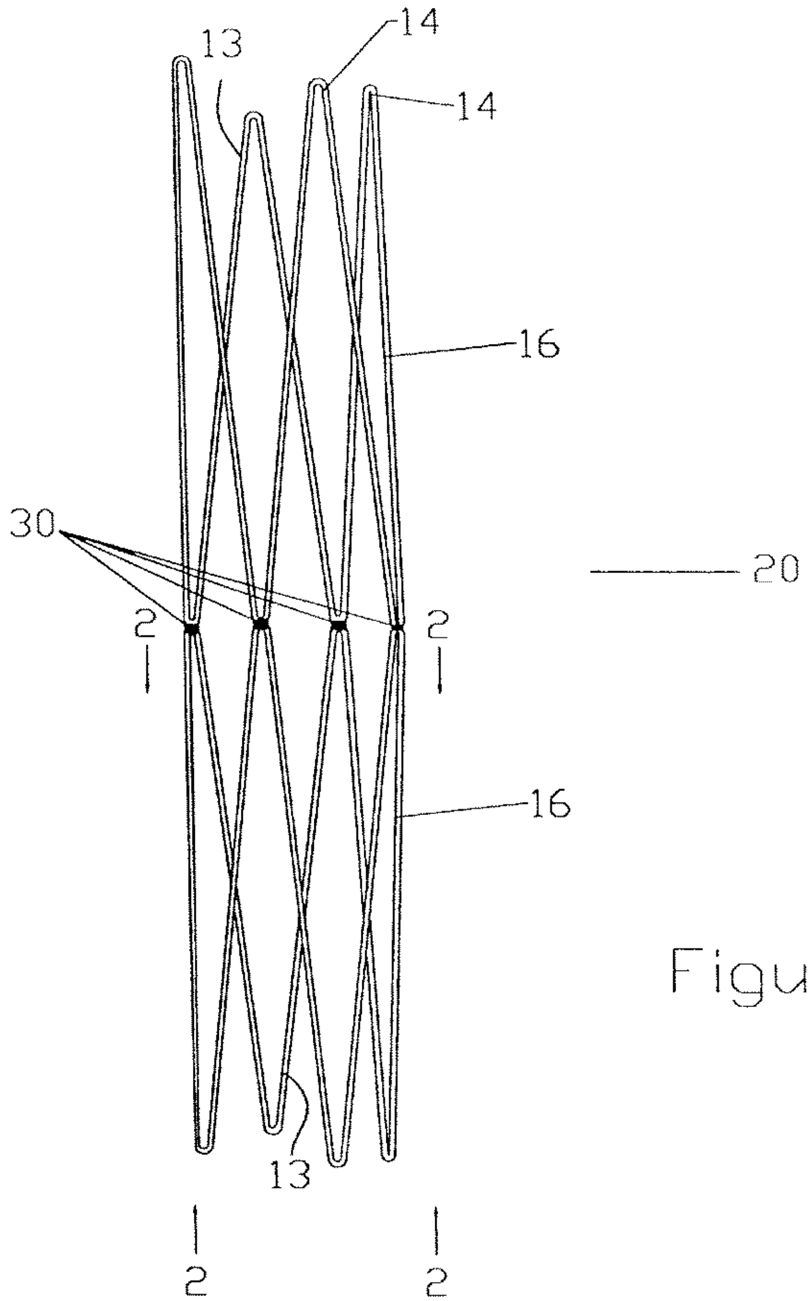


Figure 2

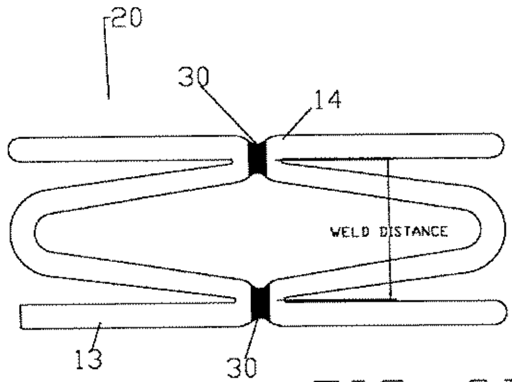


FIG. 3B

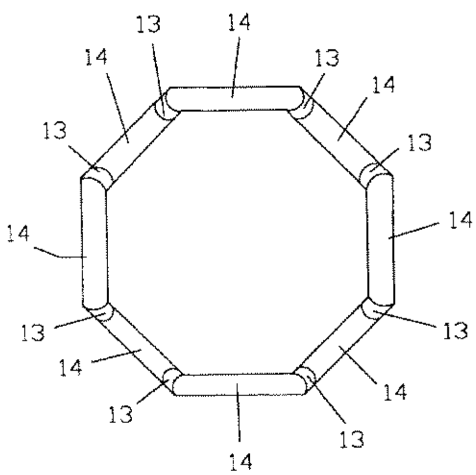


FIG. 4A

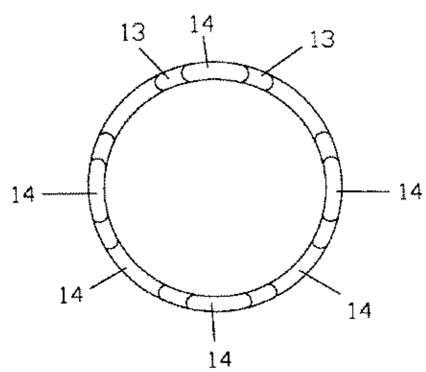


FIG. 4B

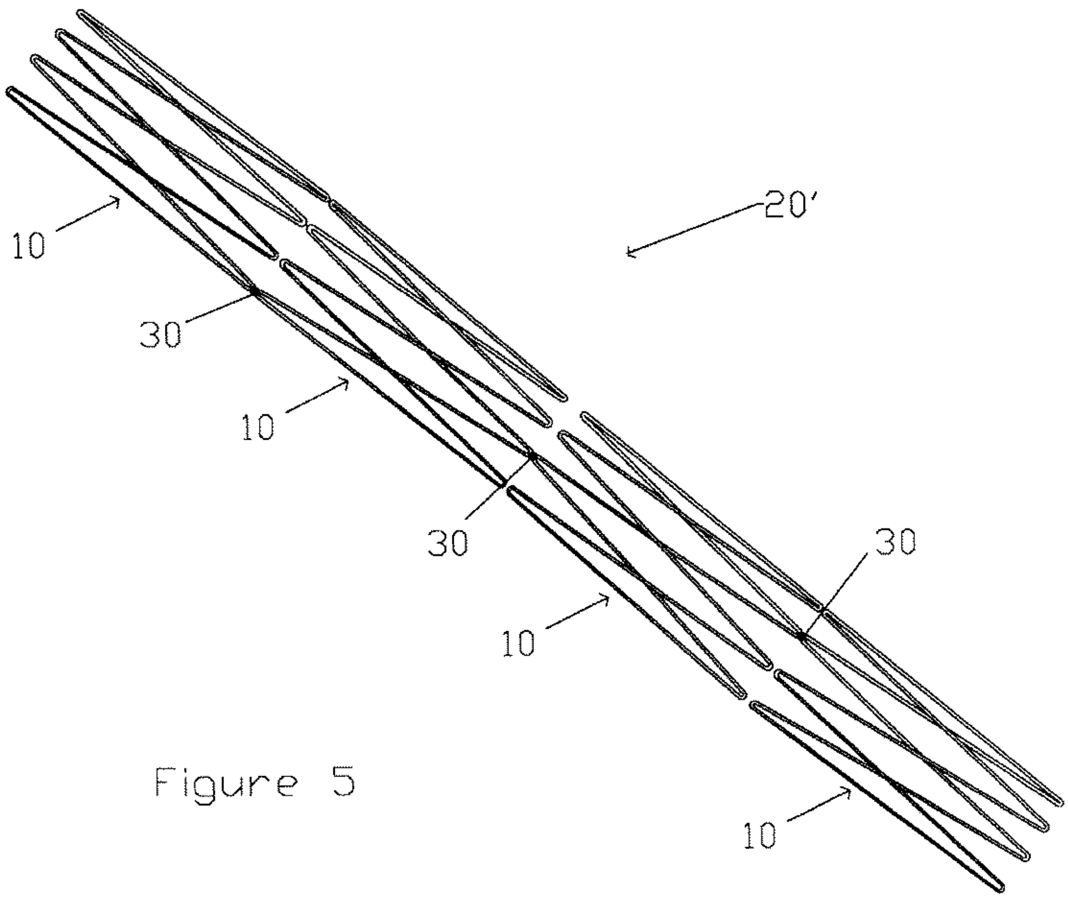


Figure 5

CONNECTED STENT APPARATUS

This application is a continuation-in-part of U.S. Pat. application Ser. No. 08/326,024, filed on Oct. 19, 1994 now abandoned.

FIELD OF THE INVENTION

This invention relates to medical implant devices, and more specifically to a connected implantable stent apparatus consisting of at least two short stent segments connected by welding, or by using other methods producing substantially rigid joints, and particularly suitable for the treatment of coronary or peripheral vessels in humans.

BACKGROUND OF THE INVENTION

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods and devices for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

An important development for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon within the narrowed lumen of the coronary artery. Radial expansion of the coronary artery occurs in several different dimensions, and is related to the nature of the plaque. Soft, fatty plaque deposits are flattened by the balloon, while hardened deposits are cracked and split to enlarge the lumen. The wall of the artery itself is also stretched when the balloon is inflated.

Angioplasty is typically performed as follows: A thin walled hollow guiding catheter is introduced into the body via a relatively large vessel, such as the femoral artery in the groin area or the brachial artery in the arm. Access to the femoral artery is achieved by introducing a large bore needle directly into the femoral artery, a procedure known as the Seldinger Technique. Once access to the femoral artery is achieved, a short hollow sheath is inserted to maintain a passageway during the procedure. The insertion of the flexible guiding catheter involves the negotiation of an approximately 180 degree turn through the aortic arch to allow the guiding catheter to descend into the aortic cusp where entry may be gained to either the left or the right coronary artery, as desired.

After the guiding catheter is advanced to the ostium of the coronary artery to be treated by angioplasty, a flexible guidewire is inserted into the guiding catheter through a balloon (described infra) and advanced to the area to be treated. The guidewire provides the necessary steerability for passage through the lesion. The guidewire is advanced across the lesion, or "wires" the lesion, in preparation for the advancement of a balloon catheter composed of polyethylene, polyvinyl chloride, polyolefin, or other suitable substance across the guide wire. The balloon, or dilatation, catheter is placed into position by sliding it along the guide wire. The use of the relatively rigid guide wire is necessary to advance the catheter through the narrowed lumen of the artery and to direct the balloon, which is typically quite flexible, across the lesion. Radiopaque markers in the balloon segment of the catheter facilitate positioning across the lesion. The balloon catheter is then inflated with contrast material to permit fluoroscopic viewing during

treatment. The balloon is alternately inflated and deflated until the lumen of the artery is satisfactorily enlarged.

Unfortunately, while the affected artery can be enlarged, in some instances the vessel restenoses chronically, or closes down acutely, negating the positive effect of the angioplasty procedure. In the past, such restenosis frequently necessitated repeat PTCA or open heart surgery. While such restenosis does not occur in the majority of cases, it occurs frequently enough that such complications comprise a significant percentage of the overall failures of the PTCA procedure, for example, twenty-five to thirty-five percent of such failures.

To lessen the risk of restenosis, various devices have been proposed for mechanically keeping the affected vessel open after completion of the angioplasty procedure. Such mechanical endoprosthetic devices, which are generally referred to as stents, are typically inserted into the vessel, positioned across the lesion, and then expanded to keep the passageway clear. Effectively, the stent overcomes the natural tendency of the vessel walls of some patients to close back down, thereby maintaining a more normal flow of blood through that vessel than would be possible if the stent were not in place.

Various types of stents have been proposed, although to date none has proven completely satisfactory. One proposed stent involves a tube of stainless wire braid. During insertion, the tube is positioned along a delivery device, such as a catheter, in a compressed configuration which extends the tube along the catheter, making the tube diameter as small as possible. When the stent is positioned across the lesion, it is expanded, causing the length of the tube to contract and the diameter to expand. Depending on the materials used in construction of the stent, the tube maintains the new shape either through mechanical force or otherwise

The Palmaz stent (U.S. Pat. No. 4,733,665) involves what may be thought of as a stainless steel cylinder having a number of slits in its circumference, resulting in a mesh when expanded. The stainless steel cylinder is delivered to the affected area by means of a balloon catheter, and is then expanded to the proper size by inflating the balloon.

Significant difficulties have been encountered with known prior art stents, including failure to readily conform to the vessel shape, and including lack of flexibility which is required to track through, and to be implanted in, tortuous vascular anatomy. In addition, the relatively long length of most prior art stents has made it difficult to treat curved vessels, and has also effectively prevented successful implantation of multiple stents.

One solution to this problem is to implant short discrete stent segments that would make up the length of the stenosis to be stented. However, short stent segments have proven to be somewhat unstable with respect to positional stability. These and other complications have resulted in a low level of acceptance for such stents within the medical community, and to date stents have not been accepted as a practical method for treating chronic restenosis.

Boneau U.S. Pat. No. 5,292,331 provides a unitary wire-like stent structure configured to form a plurality of upper and lower axial peaks, and is delivered and expanded in a manner similar to delivery of the prior art stents described above. The low mass and relatively short length of the Boneau stent increased steerability through curved vessels. Copending U.S. Pat. application Ser. No. 08/326,024 describes methods of connecting one or more Boneau stents using suture materials, short lengths of wire or ribbon, and internally or externally mounted sleeves.

SUMMARY OF THE INVENTION

A connected stent embodying the principles of the present invention defines an endoprosthetic device or single stent comprised of at least two short stent segments interconnected by welding, or by other methods producing a substantially rigid joint, for example soldering, rigid adhesive, etc. to enable selection of a stent tailored to the dimensions of the lesion to be treated, and to maintain positional stability within the vasculature. Interconnection of discrete stent segments occurs preferably by welding corresponding axial turns, or crowns, on aligned adjacent stent segments.

Alternatively, for increasing the flexibility of three or more welded stent segments, the number of welds is decreased by welding in a substantially spiral, or alternating pattern which does not include welds at all adjacent crowns. In this embodiment, the stent segments themselves are sufficiently flexible to enable the connected stent to maneuver through and conform to the often tortuous vessels requiring treatment. The preferred embodiment uses stent segments having four crowns at each end with welds at each adjacent crown area of the connected stent. The stent segments having at least one pair of axially aligned adjacent crown areas.

In broadest terms, the connected endovascular stent apparatus of this invention provides a plurality of short discrete stent segments each forming a cylinder, each cylinder having an inside, outside, and at least one end surface, with at least one set of axial turns, or crowns, on corresponding end surfaces on adjacent stent segments connected by a method producing a substantially rigid joint between crowns. The inventive stent apparatus may be formed from a plurality of single pieces of wire, each formed into sections to define an expandable stent, and joined together as described herein. The resultant stent apparatus can then be compressed onto a balloon catheter, delivered to the affected vessel and expanded in place, all as described herein. Additionally, multiple connected stents can be spaced apart and compressed onto a balloon catheter for delivery to the affected vessel.

The stent, or endovascular support device, of the present invention may preferably be comprised of implantable quality high grade stainless steel or other implantable material, machined specially for intravascular applications. The inventive stent segments may comprise a plurality of circles or ellipsoids formed to create a plurality of axial bends, thereby permitting compression of the connected stent onto a delivery catheter, and subsequent expansion once in place at the affected area.

The deployment methods for the connected inventive stent apparatus may include balloon expanding, self-expanding, self-retracting, and mechanically expanding. Some of the intended uses include PTCA type stenting, PTA type stenting, graft support, graft delivery, INR use, GI tract use, drug delivery, and biliary stenting.

A general object of the present invention is to provide a connected stent that overcomes the drawbacks and limitations of the prior art.

A specific object of the present invention is to provide a connected stent comprised of at least two, short stent segments connected by a method producing a substantially rigid joint and having a length sufficient to maintain positional stability when implanted.

Another specific object of the present invention is to provide a connected stent comprised of short stent segments of low mass formed of straight segments integrally joined at axial bends (crowns) wherein individual, adjacent short segments are welded together at one or more adjacent crowns.

One more specific object of the present invention is to provide a connected stent comprised of at least three short stent segments wherein the welds form a spiral or alternating pattern around the generally circular, or elliptical, connected stent thereby welding at a single adjacent crown area in each plane of the stent.

An additional object of the present invention is to provide a connected, welded stent having stent segments sufficiently flexible so that a spiral or alternating pattern of rigid welds allows the connected stent to be maneuvered through and implanted in highly curved vessels.

Yet another object of the present invention is to provide a connected stent made from a plurality of short stent segments to enable a single connected stent, or multiple connected stents, to be tailored to the dimensions of the particular area to be treated.

These and other objects, advantages and features of the present invention will become more apparent upon considering the following detailed description of a preferred embodiments, presented in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side sectional view of a stent segment in its expanded configuration taken along lines **2**—**2** in FIG. **2**.

FIG. **2** is a side elevational view of a connected stent embodying principles of the present invention and showing two, short, discrete stent segments of FIG. **1** connected at adjacent axial turns, or crowns, by welds.

FIG. **3**A is an enlarged side sectional view of the assembled connected stent of FIG. **1**, prior to deployment and expansion, taken along lines **2**—**2** and showing the welded crown areas. FIG. **3**B shows the section view in its deployed configuration.

FIG. **4**A is an end view of the connected stent prior to deployment and expansion, and FIG. **4**B is an end view of the deployed and expanded connected stent.

FIG. **5** is a side view of a preferred connected stent having four stent segments connected by a pattern of welds spiraling around the connected stent.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. **1** is a side sectional view of a preferred stent segment **10** for forming a connected stent embodying the principles of the present invention. The stent segment **10** comprises a single wire **12** bent into a plurality of straight sections **13** integrally joined by discrete axial turns, or crowns **14** and forming a cylinder **16**, as best shown in FIG. **2**. In the preferred stent segment **10**, the straight sections **13** and the crowns **14** have substantially the same cross-sectional dimensions.

The stent segment **10** is preferable formed from implantable materials having good mechanical strength, such as implantable quality stainless steel wire. The outside of the stent segment may be selectively plated with platinum or other radiopaque materials to provide improved visibility during fluoroscopy. The cross-sectional shape of the finished stent segment **10** may be circular, ellipsoidal, rectangular, hexagonal, square, or another polygon, although at present it is believed that circular or ellipsoidal may be preferable.

Referring now to FIGS. **2** and **3**A, a connected stent **20** is formed from two or more stent segments **10** by aligning the

stent segments **10** end to end so that corresponding crowns **14** are adjacent. The connected stent **20** is formed by a weld **30** between at least one set of corresponding axial turns **14** or crowns on the adjacent stent segments **10**. Any welding or rigid joint forming material suitable for implantation into the body may be used, and it is preferred to use the same stainless steel for both the stent segments **10** and the welds **30**. The welds **30** are approximately the same width as the cross-sections of the crowns **14** and sections **13**. The length of the welds **30** is selected so that approximately one quarter of the diameter of the crown **14** is not welded. The welds **30**, which are substantially rigid, are made as small as possible to reduce the mass and maintain the flexibility of the connected stent **20**, the segments **10** thereof which are inherently somewhat flexible.

As shown in FIG. **2**, welds **30** may be placed at each adjacent crown **14** area around the cylindrical connected stent, and four welds **30** are shown. Alternatively as best shown in FIG. **5**, welds **30** may be placed at only one adjacent crown pair between two adjacent stent sections **10**. FIG. **5** shows a connected stent **20**' having four stent segments **10**. The welds **30** form a spiral pattern around the cylindrical stent **20**'. The spiral pattern shown in FIG. **5**, or an alternating pattern, reduces the number of welds **30** thereby maintaining the flexibility of the connected stent **20**'.

It will be recognized by those skilled in the art that the number of axial turns (crowns **14**) in each stent segment **10** may vary, generally between two and ten with the optimum being four to seven, and that the number of welds **30** may vary accordingly. At least one weld **30** is required to connect two stent segments **10**, and it is preferable to space welds in a balanced fashion in the spiral or alternating configuration. Alternatively, the welds **30** may be selectively placed to more easily selectively configure a connected stent to the contours of the vessel to be treated.

FIG. **3**B shows the increased spacing between the straight sections **13** following application of a radially expansive force to expand the connected stent **20** into its deployment position. A comparison of FIG. **3**A and **3**B shows that expansion causes the angle of the crown **14** to increase, and causes the distance between welds **30** to increase. The comparison between the non-expanded and the expanded configuration may also be seen in FIG. **4**A (non-expanded) and FIG. **4**B (expanded). The crowns **14** can be seen to permit each stent segment **10** to be compressed or expanded over a wide range while still maintaining a significant mechanical force, such as required to prevent a vessel from restenosing.

The minimum length of the connected stent **20** or **20**' is determined in large measure by the size of the vessel into which the stent **20** will be implanted. The connected stent **20** will preferably be of sufficient length to maintain its axial orientation with the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the connected stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis. Typical cardiovascular vessels into which the connected stent **20** might be implanted range from 1.5 millimeters to six millimeters in diameter, and corresponding connected stents **20** may range from approximately 4 millimeters to four centimeters in length.

Due to the conformability of the single weld connected stent, not only can varying lesion lengths be treated, but curved vessels and multi-curved vessels may also be treated.

Once the configuration of the connected stent has been selected and the stent is welded to form the selected configuration, the connected stent may be crimped onto a balloon of a balloon catheter device for delivery to the affected region of a vessel such as a coronary artery. Once the balloon is in place across the lesion, using conventional imaging techniques and radiopaque dyes, the balloon may be inflated, again substantially in a conventional manner, to deploy the connected stent. In selecting a balloon, it is helpful to ensure that the balloon will provide radially uniform inflation so that the connected stent will expand equally along each of the segments. The inflation of the balloon causes the expansion of the stent. The amount of inflation, and commensurate amount of expansion of the connected stent, may be varied as dictated by the lesion itself, making the connected stent of the present invention particularly flexible in the treatment of chronic restenosis.

Because of the inflation of the balloon, the lesion in the vessel is compressed, or cracked, and the lumen is expanded accordingly when the wall of the vessel to pressed outwardly radially. At the same time, the plaque deposited within the intima of the vessel is displaced and thinned, and the stent is embedded in the plaque or other fibrotic material adhering to the intima of the vessel.

Following inflation of the balloon and expansion of the connected stent within the vessel, the balloon is deflated and removed. The exterior wall of the vessel attempts to return to its original shape through elastic recoil. The stent, however, remains in its expanded form within the vessel, and prevents further restenosis of the vessel. The stent maintains an open passageway through the vessel, so long as the tendency toward restenosis is not greater than the mechanical strength of the stent. Because of the low mass of the support device of the present invention, thrombosis is less likely to occur. Ideally, the displacement of the plaque deposits and the implantation of the stent will result in a smooth inside diameter of the vessel.

While the primary application for the connected stent is presently believed to be treatment of cardiovascular disease such as atherosclerosis or other forms of coronary narrowing, the stent of the present invention may also be used for treatment of narrowed vessels in the kidney, leg, carotid, or elsewhere in the body. In such other vessels, the size of the connected stent may need to be adjusted to compensate for the differing sizes of the vessel to be treated.

While this invention has been described in connection with preferred embodiments thereof, it is obvious that modifications and changes therein may be made by those skilled in the art to which it pertains without departing from the spirit and scope of the invention. For instance, other stents may be axially aligned and connected by welds without departing from the spirit and scope of the invention. Accordingly, the aspects discussed herein are for illustration only and should not limit the scope of the invention herein which is defined by the claims.

What is claimed is:

1. A connected endovascular support device for implantation in a vessel within the human body comprising:

at least two unitary wire-like generally circular members each bent to form a plurality of substantially straight, non-overlapping segments connected at axial bends;

the at least two generally circular members having at least one pair of aligned axial bends; and

the at least two circular members connected by at least one substantially rigid joint at least one pair of aligned axial bends.

2. The connected support device of claim 1 wherein all axial bends are aligned and connected by a substantially rigid joint.

3. The connected support device of claim 1 wherein selected aligned axial bends are connected by substantially rigid joints to form a generally spiral pattern of joints around the support device.

4. The connected support device of claim 1 wherein selected aligned axial bends are connected by substantially rigid joints to form an alternating pattern of joints around the support device.

5. The connected support device of claim 1 wherein the substantially rigid joint is a weld.

6. A connected stend apparatus comprising:

at least three adjacent short discrete stent members, each formed of a plurality of substantially straight, non-overlapping segments integrally connected at axial bends;

at least one pair of aligned axial bends between adjacent stent members; and

said at least one pair of aligned axial bends between adjacent stent members being connected by a substantially rigid joint.

7. The connected stent according to claim 6 wherein said connected aligned axial bends form a generally spiral pattern of substantially rigid joints around the stent apparatus.

8. The connected stent according to claim 6 wherein said connected aligned axial bends form an alternating pattern of substantially rigid joints around the stent.

9. The connected stent according to claim 6 wherein all axial bends between adjacent stent members are aligned.

10. The connected stent according to claim 9 wherein all aligned axial bends are connected by substantially rigid joints.

11. The connected stent according to claim 6 wherein the substantially rigid joint is a weld.

12. The connected stent according to claim 6 wherein the stent members have a generally ellipsoidal cross-sectional shape.

13. The connected stent according to claim 6 wherein the stent members have a generally circular cross-sectional shape.

14. A connected stent apparatus comprising:

a first generally tubular member having first and second ends and comprising a plurality of substantially straight, non-overlapping segments connected at axial bends;

a second generally tubular member having first and second ends and comprising a plurality of substantially straight, non-overlapping segments connected at axial bends;

wherein one axial bend at the first end of the first generally tubular member is connected by a substantially rigid joint to one axial bend of the first end of the second generally tubular element; and

wherein said first and second generally tubular members are non-overlapping.

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